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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,406	01/22/2001	Michael S. Halpern	7933-38	5749

7590 02/10/2004

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EXAMINER
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YAEN, CHRISTOPHER H

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/744,406	<b>Applicant(s)</b> HALPERN ET AL.	
	<b>Examiner</b> Christopher H Yaen	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 November 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3,7-10,12,16-18,34,35 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,7-10,12,16-18,34,35 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The amendment filed 11/07/2003 is acknowledged and entered into the record. Accordingly, claims 2, 4-5, 11, 13-15, 19-33, and 36-38 are canceled without prejudice or disclaimer, and claim 39 is newly added.
2. Claims 1, 3, 7-10, 12, 16-18, 34-35, and 39 are pending and examined on the merits.

### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

3. The rejection of claim 1, 3, 7-10, 12, 16-18, 34-35, and 39 under 35 USC 112, 1<sup>st</sup> paragraph as lacking proper written description is maintained for the reasons of record. Applicant argues that the examiner's has misinterpreted the claimed invention as being any cellular immunogen, but is rather a cellular immunogen which is allogeneic with respect to the the host and which has been transfected with at least one transgene which is cognate to the target protooncogene. Applicant further argues that the specification as originally filed has provided a clear possession the multiple cellular immunogen by providing a list of target proto-oncogenes, screening methods, and methods of transfection into cells to generate the allogeneic cellular immunogens. Applicant's arguments have been carefully considered but are not found persuasive to overcome the rejection of record.

It is clear to the examiner that the invention was drawn to a cellular immunogen that is allogenic with respect to the host and that is transfected with a transgene that is cognate to the target proto-oncogene. However, the claims as interpreted seems to

encompass transgenes which have not been disclosed or described in the specification. Further, the working examples provided do not seem to provide adequate written description for the genus of transgenes claimed. In order for a specification to comply with written description, it must convey to one of skill in the art that the inventor was in possession of the invention as claimed. The instant specification provides two working examples of two specific transgenes. From these examples, the skilled artisan would not be able to make a reasonable correlation between what is taught and what is claimed. Furthermore, the artisan cannot determine with reasonable predictability that the examples are representative of all the transgenes disclosed in Table II. The only relation between the transgene that were actually reduced to practice and those that are desired is that they are in so way related to an oncogeneic transformation of a cell. There is no structural correlation or functional relationship between the genus of transgenes claimed and the species reduced to practice. In addition, there does not appear to be a clear correlation between the structures of the two examples provided with structures or functions of the all the disclosed transgenes, so as to indicating to one of skill in the art that the species taught are in deed representative of the entire genus of transgenes claimed.

**All other rejections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in Paper No. 11/07/2003.**

### ***Conclusion***

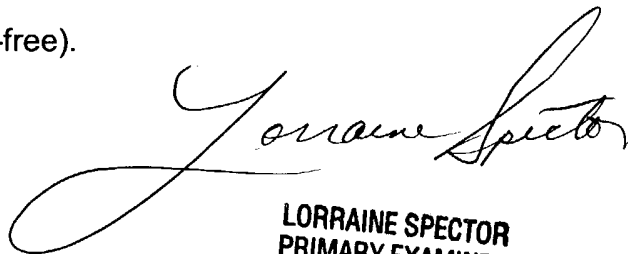
No claim is allowed. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
LORRAINE SPECTOR  
PRIMARY EXAMINER

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Art Unit: 1642

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Christopher Yaen  
Art Unit 1642  
February 5, 2004